

**Premarket Notification 510(k)
ORTHO™ Sera Papain
510(k) Summary (as required by 21 CFR 807.92(a))**

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This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Submitter:

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Manufacturer and Manufacturing Site:

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Date:

April 16th, 2015

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B. Name of Device:

ORTHO™ Sera Papain

Alba Bioscience Limited Product Code:

FD317

Catalogue Number:

6904840

Common Name:

Solution, Stabilized Enzyme

Proprietary Name:

ORTHO™ Sera Papain

Device Class:

ORTHO™ Sera Papain is a class II IVD medical device according to the stipulations of 21 CFR 864.9400.

Regulation Number and Product Code:

Regulation Number: 864.9400

US FDA Product Code: KSK

Classification Panel:

Hematology

C. Predicate(s):

ALBAzyme™ Papain Solution Kit (510(k) Number: BK140144, Product Code: KSK).

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D. Device Description:

ORTHO™ Sera Papain consists of 4 vials, each containing 5 mL of Papain Enzyme Solution.

E. Indications for Use:

For *in vitro* diagnostic use only.

For use as an enzyme solution with ORTHO™ Sera Anti-Le^a, Anti-Le^b, Anti-Jk^a and Anti-Jk^b Blood Grouping Reagents.

F. Substantial Equivalence Comparison and Discussion:

Table 1 below presents a direct comparison of ORTHO™ Sera Papain and the ALBAzyme™ Papain Solution Kit product (510(k) Number: BK140144).

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Table 1 – Comparison of ORTHO™ Sera Papain and the ALBAzyme™ Papain Solution Kit

	ORTHO™ Sera Papain	ALBAzyme™ Papain Solution Kit
Device Classification Name	Solution, Stabilized Enzyme	Solution, Stabilized Enzyme
Product Code	KSK	KSK
US FDA Classification	Class II	Class II
US FDA Regulation Number	864.9400	864.9400
US FDA Review Panel	Hematology	Hematology
Intended use	For use as an enzyme solution with ORTHO™ Sera Anti-Le ^a , Anti-Le ^b , Anti-Jk ^a and Anti-Jk ^b Blood Grouping Reagents.	ALBAzyme™ Papain Solution Kit is used for the preparation and testing of papainized red blood cells.
Intended Use Clarification	The ORTHO™ Sera Papain is used to enhance reactivity of ORTHO™ Sera red blood cell antigen typing reagents and red blood cells when used in <i>in vitro</i> immunohematology assays.	The ALBAzyme™ Papain Solution is used to treat human red blood cells with papain for use in <i>in vitro</i> immunohematology assays, and the ALBAzyme™ Enzyme Control reagent is for the quality control of papainized red blood cells prior to use.
Intended User(s)	<i>In vitro</i> diagnostic (IVD) device for professional use only.	<i>In vitro</i> diagnostic (IVD) device for professional use only.
Reagent	4 vials, each containing 5 mL of Papain Enzyme Solution.	2-vial kit, one vial each of Papain Solution (1 x 3mL) and Enzyme Control (1 x 5mL).
Enzyme Component/Type	Papain – Proteolytic Enzyme.	Papain – Proteolytic Enzyme.
Control Type	Not applicable.	<i>Glycine soja</i> Lectin
Mode of Action	Enhancement of antigen/antibody reactions.	Enhancement of antigen/antibody reactions.
No. of Vials	4	2
Trade Dress	Ortho Clinical Diagnostics	Quotient

From Table 1 above, it can be ascertained that ORTHO™ Sera Papain and the ALBAzyme™ Papain Solution Kit are substantially equivalent with regards to the following parameters; classification, intended use and mode of action. Each product contains the proteolytic enzyme, Papain.

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ORTHO™ Sera Papain contains Papain Enzyme Solution as does the ALBAzyme™ Papain Solution Kit. An additional Enzyme Control, as contained within the ALBAzyme™ Papain Solution Kit, is not required for use with ORTHO™ Sera Papain. Consequently, the provision of this additional reagent with the Alba Bioscience Limited product has no impact on the substantial equivalence claimed between ORTHO™ Sera Papain and the ALBAzyme™ Papain Solution Kit.

Comparator Testing was performed over 4 trial sites and this data is presented, and discussed fully, in sections 18, 'Performance Testing – Bench' and 20, 'Performance Testing – Clinical' (and the associated Appendix) of this 510(k) submission. The results produced from these comparator studies confirmed that ORTHO™ Sera Papain is suitable for use with ORTHO™ Sera reagents to enhance reactivity of Anti-Le^a, Anti-Le^b, Anti-Jk^a and Anti-Jk^b blood grouping reagents, and is comparable to the ALBAzyme™ Papain Solution Kit, with regards to safety and effectiveness for the intended purpose of use as an enzyme solution.

G. Performance Testing:

Performance evaluation of ORTHO™ Sera Papain was undertaken at 4 trial sites; Alba Bioscience Ltd (Edinburgh), Blood Center Wisconsin (Milwaukee), Memorial Blood Center (Minneapolis) and New York Blood Center (New York City).

In addition, an internal laboratory study has been undertaken to provide further evidence to support substantial equivalence of ORTHO™ Sera Papain to the appropriate component of the US legally marketed predicate device ALBAzyme™ Papain Solution Kit (BK140144), a reagent kit to perform and confirm enzyme treatment of red blood cells.

Performance evaluation data obtained from the 4 trial sites for the respective ORTHO™ Sera blood grouping reagents (Anti-Le^a, Anti-Le^b, Anti-Jk^a and Anti-Jk^b) used with the ORTHO™ Sera Papain achieved greater than 99% agreement with the respective US licensed comparator reagents in testing of over 1000 samples. These

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samples included donor and clinical test subjects that were collected into routinely used anticoagulants, as appropriate. The red blood cell samples tested reflected the demographic population of the US and also included diseased state samples as they routinely presented. The trial reagents were therefore considered to have demonstrated their suitability for the determination of Le^a, Le^b, Jk^a and Jk^b antigens on human red blood cells when used in conjunction with ORTHO™ Sera Papain on the ID-MTS™ system.

For the internal laboratory study, the trial and predicate papain solutions were used in parallel according to the Instructions for Use for the corresponding ORTHO™ Sera typing reagent. The study demonstrated substantial equivalence of the trial and predicate papain solutions in use for the enzyme treatment of red blood cells and also in the enhancement of activity of the ORTHO™ Sera reagents (Anti-Le^a, Anti-Le^b, Anti-Jk^a and Anti-Jk^b) when added to the assay on the ID-MTS™ system. In all testing performed the trial reagent, ORTHO™ Sera Papain achieved a comparable test outcome demonstrating substantial equivalence to the US legally marketed predicate device ALBAzyme™ Papain Solution Kit (BK140144).

The results of these studies are presented and discussed fully in 'Performance Evaluation Report ORTHO™ Sera Papain, Product Code FD317, PE15-P0029.2-FD317-RPT', which is included as Appendix 7 of this 510(k) submission.

H. Summary of Software:

ORTHO™ Sera Papain has not been designed with any software device components or accessories, nor is it intended to be used in combination with any software device. Consequently, this section is not applicable to ORTHO™ Sera Papain as this device does not require software to fulfil its intended use (as stipulated in the Instructions for Use for this device).

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I. Compliance with FDA Guidance and Consensus Standards:

ORTHO™ Sera Papain has not been designed or manufactured in conjunction with any US FDA consensus standards.

J. Conclusion:

ORTHO™ Sera Papain is a Class II IVD medical device according to the stipulations of 21 CFR 864.9400. This product is substantially equivalent, to US-legally marketed predicate, the ALBAzyme™ Papain Solution Kit product (510(k) Number: BK140144).

Substantial equivalence has also been demonstrated via comparator studies conducted at 4 discrete trial sites along with an internal study, and subsequent analysis of results obtained (please refer to section G above).

Performance Evaluation studies have also confirmed that the ORTHO™ Sera Papain is 'fit for purpose', i.e. is suitable for its intended use, as stated in the Instructions for Use for this device. No issues with safety or effectiveness are anticipated for this device.